MAR 2 8 2014

K122298
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EXHIBIT 4 (Page 1 of 2)
510 (k) Summary

June 14, 2013

1. Submitter:

Company:	JPI Healthcare Solutions
	52 Newtown Plaza
	Plainview, NY 11803
Telephone:	516-513-1330 ext 108
Contact:	William Little

2. Identification of Device:

Proprietary-Trade Name:	AJEX 1200H and AJEX 240H Portable X-ray Units
Classification Name:	Mobile X-ray System
Product Code:	90 IZL
Common/Usual Name:	Portable general Purpose X-ray Unit.

3. Equivalent Marketed Devise:

This product is substantially equivalent to the MinX-ray HF100+ and HF120/610Hz PowerPlus Portable X-ray units (Predicate Device), which have been found to be substantially equivalent through the 510 (k) premarket notification process.

4. Description of Device:

The AJEX 1200H and AJEX 240H are portable x-ray units which operate at 110V or 220V, 50/60 HZ. The units have an LED display with up and down soft keys to control KvP. In addition the unit has preset memory keys to store and select KvP. The units can be installed on a mobile stand, a support arm or can be hand held. The unit should be used only by qualified/trained doctor or technician on both adult and pediatric subjects for taking diagnostic radiographic exposures of body parts. The usual safety precautions regarding the use of x-ray units must be observed by the operator.

5. Intended Use of AJEX 1200H AND AJEX 240H:

This equipment is used for generating X-ray to get the X-ray image for the purpose of diagnosis of patient.
This equipment is possible to move the place for patient because it is designed for portable type.
This equipment is possible to combine with the mobile stand unit for convenience for patient positioning according to user's needs.
The AJEX 1200H/ AJEX 240H Mobile X-ray Generator is designed for the following applications :
- Physician with general practice
- Bedside exposures in hospital ward
- Surgery and orthopedics

EXHIBIT 4 (Page 2 of 2)
510 (k) Summary

6. Substantial Equivalence Chart

Characteristics	**HF100+**	**HF120/60Hz PowerPlus**	**AJEX-1200H**	**AJEX-240H**
Intended use.	SAME	SAME	SAME	SAME
MA	20,25,30	14-60	15-80	15-40
kVp	40-100	40-120	40-120	40-120
mAs		0.6-212	0.6-168	0.4-140
Focal Spot	1.2mm	1.2mm	1.8mm	1.2mm
Power requirement	100-140VAC or 200-260VAC, 50/60Hz	100-260VAC, 50/60Hz	110 or 220V, 50/60Hz	110 or 220V, 50/60Hz
User Interface	Exposure Switch and Console	Exposure Switch and Console	Exposure Switch and Console	Exposure Switch and Console
Collimator	manual	manual	manual	manual
Size	9.5"x 8.75" x 16"	16"x8.8"x9.5"	13.4" x 9.9" x 9.8"	13.4" x 7.6" x 6.4"
Weight	45.5lbs	38.6lbs	44lbs	32lbs

7.

Conclusion:

After analyzing all the data it is the conclusion of JPI that the AJEX-1200H and 240H are as safe and effective as the predicate devise. The systems have few technological differences, and have no new indication for use, thus rendering them substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

March 28, 2014

AJEX Meditech, Ltd.
% Mr. William Little
Product Manager
JPI Healthcare Solutions, Inc.
52 Newtown Plaza
PLAINVIEW NY 11803

Re: K122298
Trade/Device Name: AJEX 1200H and AJEX 240H Portable X-ray Units
Regulation Number: 21 CFR 892.1720
Regulation Name: Mobile x-ray system
Regulatory Class: II
Product Code: IZL
Dated: November 8, 2013
Received: November 12, 2013

Dear Mr. Little:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

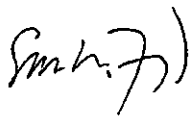
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K122298

Device Name
AJEX 1200H I AJEX 240H Mobile X-ray Generator

Indications for Use *(Describe)*
This equipment is used for generating X-ray to get the X-ray image for the purpose of diagnosis of patient.

This equipment is possible to move the place for patient because it is designed for portable type.

This equipment is possible to combine with the mobile stand unit for convenience for patient positioning according to user's needs.

The AJEX 1200H/ AJEX 240H Mobile X-ray Generator is designed for the following applications :

- Physician with general practice

- Bedside exposures in hospital ward

- Surgery and Orthopedics

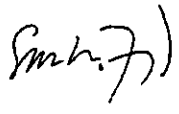
Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*



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